	ORA LABORATORY POLICIES FOOD AND DRUG ADMINISTRATION	DOCUMENT NO.: ORA-LAB.QM	VERSION NO.: 1.9
			PAGE 1 OF 2
TITLE: ORA LABORATORY MANUAL OF QUALITY POLICIES			EFFECTIVE DATE: 10-01-03 REVISED: 01-22-13

4.4 Review of Requests, Tenders and Contracts

4.4.1 Review

ORA, Division of Planning, Evaluation and Management (DPEM) develops and issues the Annual Fiscal Year (FY) Workplan for ORA field units. The portion of the workplan concerned with the laboratories is a cooperative effort among the Centers, ORA Field Committee, and ORS. The workplan is based on several factors such as the budget, the number of analysts and amount of resources, the Commissioner's performance goals, the compliance program accomplishment goals, the inventory of regulated industry maintained by the field units, and FDA-targeted products. Distribution of assignments is by Program Assignment Code (PAC) and full time equivalent (FTE) hours within the different program areas. The compliance programs specify or cite the methods for analyses. The ORA laboratories and ORS review the annual workplan to ensure that each laboratory has the capability and resources to provide the requested services. Any differences between the workplan and the laboratory capability are resolved in accordance with ORA-ORM.003, ORA Workplanning process or through consultation with District/Regional management.

In addition to the workplan, assignments may be issued to ORA laboratories by an ORA headquarters unit or a Center. Multiple district assignments and high priority requests for work are approved according to FDA Field Management Directive 17, ORA Field Assignments-Guidelines for Issuance by Headquarters. Such assignments are cleared through the Office of Operations (OO). Assignments specify or cite the methods for analyses. Requests not covered by compliance programs or assignments are reviewed prior to receipt of samples by the laboratory's management when possible.

The results of this process are discussed and documented as part of the laboratory's annual management review.


4.4.2 Records of Review

ORA laboratories maintain records of workplan reviews, changes, and change requests. Records are also maintained of discussions regarding ad hoc assignments.

4.4.3 Subcontracting Laboratories

The policies regarding the use of subcontracting laboratories are found in Volume I Subsection 4.5 Subcontracting of Tests. The customer requesting collaborative testing by laboratories outside of ORA is responsible for the work done by such labs. ORA is not responsible for such work under these circumstances.

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	ORA LABORATORY POLICIES FOOD AND DRUG ADMINISTRATION	DOCUMENT NO.: ORA-LAB.QM	VERSION NO.: 1.9
			PAGE 2 OF 2
TITLE: ORA LABORATORY MANUAL OF QUALITY POLICIES			EFFECTIVE DATE: 10-01-03 REVISED: 01-22-13

4.4.4 Contract Deviations

Requests for deviations from work assignments or compliance programs are processed by the Office of Regulatory Science (ORS). ORS interacts with the customer to determine whether the requested changes are acceptable. Records of contract changes are maintained.

4.4.5 Amendments to Contracts

If a contract needs to be amended after work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel named in the contract.

Related Documents

- ORA-ORM.003, ORA Workplanning Process
- FDA Field Management Directive 17, ORA Field Assignments-Guidelines for Issuance by Headquarters
- Annual Workplan